



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0190; FRL-10783-01-OCSP]

Paraffin Waxes and Hydrocarbon Waxes, Carboxypolymethylene Resin, and Paraffin Waxes and Hydrocarbon, Oxidized, Lithium Salts in Pesticide Formulations; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of paraffin waxes and hydrocarbon waxes, carboxypolymethylene resin, and paraffin waxes and hydrocarbon, oxidized, lithium salts when used as inert ingredients (flow aid, surface protectant, binder, carrier, coating agent or adjuvant) on growing crops and raw agricultural commodities pre- and post-harvest, applied in/on animals, and in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. Spring Regulatory Sciences, on behalf of Sasol Chemicals (USA) LLC, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of paraffin waxes and hydrocarbon waxes, carboxypolymethylene resin oxidized paraffin wax, and paraffin waxes and hydrocarbon, oxidized, lithium salts, when used in accordance with the terms of those exemptions.

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of

the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0190, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; main telephone number: (202) 566-2875; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180?toc=1>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0190, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send>.

comments-epa-dockets#express.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Petition for Exemption

In the *Federal Register* of March 22, 2021 (86 FR 15164, FRL-10021-44), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11450) by Spring Regulatory Sciences, 6620 Cypresswood Dr, Suite 250 Spring, TX 77379, on behalf of Sasol Chemicals (USA) LLC, 12120 Wickchester Lane, Houston, TX 77224. The petition requested that 40 CFR be amended by establishing an exemption from the requirement of a tolerance for residues of paraffin waxes and hydrocarbon waxes (CAS Reg. No. 8002-74-2); carboxypolymethylene resin (CAS Reg. No. 68153-22-0) (also known as oxidized paraffin wax); and paraffin waxes and hydrocarbon, oxidized, lithium salts (CAS Reg. No. 68649-48-9), when used as an inert ingredient (flow aid, surface protectant, binder, carrier, coating agent or adjuvant) in pesticide formulations applied to growing crops and raw agricultural commodities pre- and post-harvest under 40 CFR 180.910, applied in/on animals under 40 CFR 180.930, and in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a). For ease of reading, all three chemicals are referred to collectively as paraffin waxes in the following sections. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing

agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. When making a safety determination for an exemption for the requirement of a tolerance FFDCA section 408(c)(2)(B) directs EPA to consider the considerations in section 408(b)(2)(C) and (D). Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” Section 408(b)(2)(D) lists other factors for EPA consideration making safety determinations, *e.g.*, the validity, completeness, and reliability of available data, nature of toxic effects, available information concerning the cumulative effects of the pesticide chemical and other substances with a common mechanism of toxicity, and available information concerning aggregate exposure levels to the pesticide chemical and other related substances, among others.

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order

to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for paraffin waxes including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with paraffin waxes follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by paraffin waxes as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Paraffin waxes exhibit low levels of acute toxicity via the oral, and dermal routes of exposure and they are anticipated to have low acute toxicity via the inhalation route. Paraffin waxes are non-irritating to the eye or skin, and they are not dermal sensitizers.

The repeated-dose toxicity for paraffin waxes is low. No adverse effects were observed in a 90-day oral rat study or in a developmental toxicity study in rats up to the limit dose. No

acceptable oral chronic or carcinogenicity studies are available for paraffin waxes. However, there is low concern for genotoxicity or mutagenicity based on negative results in mammalian and bacterial genotoxicity tests. No evidence of neurotoxicity was observed in the neurotoxicity screening performed in the 90-day oral rat study and no evidence of immunotoxicity was seen in the available studies.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program>.

The hazard profile of paraffin waxes is adequately defined. Overall, paraffin waxes are of low acute, subchronic, and developmental/reproductive toxicity. No systemic toxicity is observed up to 1,000 mg/kg/day. Since signs of toxicity were not observed, no toxicological endpoints of concern or PODs were identified. Therefore, a qualitative risk assessment for paraffin waxes can be performed.

C. Exposure Assessment

1. *Dietary exposure.* In evaluating dietary exposure to paraffin waxes, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from paraffin waxes in food and drinking water as follows:

Dietary exposure (food and drinking water) to paraffin waxes may occur from foods containing these inert ingredients and from non-pesticidal uses (*e.g.*, cosmetics and personal care). However, no toxicological endpoints of concern were selected, and therefore, a quantitative dietary exposure assessment for paraffin waxes was not conducted.

2. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Although the current and proposed uses of paraffin waxes can result in residential exposures, no toxicological endpoints were selected, and therefore, it is not necessary to conduct a quantitative assessment of residential exposures and risks.

3. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Based on the lack of toxicity in the available database, EPA has not found paraffin waxes to share a common mechanism of toxicity with any other substances, and paraffin waxes do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that the paraffin waxes in this petition do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <https://www.epa.gov/pesticide->

science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.

D. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on an assessment of paraffin waxes, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children. Because there are no threshold effects associated with paraffin waxes, EPA conducted a qualitative assessment. As part of that assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to paraffin wax residues.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of paraffin waxes, paraffin waxes and hydrocarbon waxes (CAS Reg. No. 8002-74-2);

carboxypolymethylene resin (CAS Reg. No. 68153-22-0); and paraffin waxes and hydrocarbon, oxidized, lithium salts (CAS Reg. No. 68649-48-9) when used as inert ingredients (flow aid, surface protectant, binder, carrier, coating agent or adjuvant) in pesticide formulations applied to growing crops and raw agricultural commodities pre- and post-harvest under 40 CFR 180.910, applied in/on animals under 40 CFR 180.930, and in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a).

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers,

not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 9, 2023.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, amend table 1 to 180.910 by adding, in alphabetical order, an entry for “Paraffin waxes and hydrocarbon waxes (CAS Reg. No. 8002-74-2); carboxypolymethylene resin (CAS Reg. No. 68153-22-0); and paraffin waxes and hydrocarbon, oxidized, lithium salts (CAS Reg. No. 68649-48-9)” to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Table 1 to 180.910

Inert ingredients	Limits	Uses
* * * *	* *	*
Paraffin waxes and hydrocarbon waxes (CAS Reg. No. 8002-74-2); carboxypolymethylene resin (CAS Reg. No. 68153-22-0); and paraffin waxes and hydrocarbon, oxidized, lithium salts (CAS Reg. No. 68649-48-9)		Flow aid, surface protectant, binder, carrier, coating agent or adjuvant
* * * *	* *	*

3. In §180.930, amend table 1 to 180.930 by adding, in alphabetical order, an entry for “Paraffin waxes and hydrocarbon waxes; carboxypolymethylene resin; and paraffin waxes and hydrocarbon, oxidized, lithium salts” to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Table 1 to 180.930

Inert ingredients	CAS Reg. No.	Limits
-------------------	--------------	--------

* * *			* * *		
Paraffin waxes and hydrocarbon waxes; carboxypolymethylene resin; and paraffin waxes and hydrocarbon, oxidized, lithium salts.			8002-74-2; 68153-22-0; 68649-48-9		
* * *			* * *		

4. In §180.940, amend table 1 to paragraph (a) by adding, in alphabetical order, an entry for “Paraffin waxes and hydrocarbon waxes; carboxypolymethylene resin; and paraffin waxes and hydrocarbon, oxidized, lithium salts” to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions)

* * * * *

(a) * * *

Table 1 to Paragraph (a)

Inert ingredients	CAS Reg. No.	Limits
* * *	* * *	
Paraffin waxes and hydrocarbon waxes; carboxypolymethylene resin; and paraffin waxes and hydrocarbon, oxidized, lithium salts.	8002-74-2; 68153-22-0; 68649-48-9	
* * *	* * *	

* * * * *